a sufficient volume of the undiluted solution to deliver 50 milligrams of ceftizoxime per kilogram.

(4) *pH.* Proceed as directed in §436.202 of this chapter, using the undiluted solution.

(5) *Identity.* The high-pressure liquid chromatogram of the sample determined as directed in paragraph (b)(1) of this section compares qualitatively to that of the ceftizoxime working standard.

[49 FR 49286, Dec. 19, 1984; 50 FR 253, Jan. 3, 1985, as amended at 55 FR 11583, Mar. 29, 1990]

§ 442.218 Cefuroxime injectable dosage forms.

§ 442.218a Sterile cefuroxime sodium.

The requirements for certification and the tests and methods of assay for sterile cefuroxime sodium packaged for dispensing are described in § 442.18a.

[48 FR 38461, Aug. 24, 1983. Redesignated at 54 FR 40654, Oct. 3, 1989]

§ 442.218b Cefuroxime sodium injection.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Cefuroxime sodium injection is a frozen, aqueous, iso-osmotic solution of cefuroxime sodium which may contain one or more suitable and harmless buffer substances and a tonicity adjusting agent. Each milliliter contains cefuroxime sodium equivalent to 15 or 30 milligrams of cefuroxime per milliliter. Its cefuroxime content is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of cefuroxime that it is represented to contain. It is sterile. It is nonpyrogenic. Its pH is not less than 5.0 and not more than 7.5. It passes the identity test. The cefuroxime sodium used conforms to the standards prescribed by § 442.18(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(A) The cefuroxime sodium used in making the batch for potency, moisture, pH, and identity.

(B) The batch for cefuroxime content, sterility, pyrogens, pH, and identity.

(ii) Samples, if required by the Director, Center for Drug Evaluation and Research:

(A) The cefuroxime sodium used in making the batch: 10 packages, each containing 1 gram.

(B) The batch:

(*1*) For all tests except sterility: A minimum of 10 immediate containers.

(*2*) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation.

(b) *Tests and methods of assay*— Thaw the sample as directed in the labeling. The sample solution used for testing must be at room temperature.

(1) *Cefuroxime content.* Proceed as directed in § 436.343 of this chapter, except prepare the sample solution and calculate the cefuroxime content as follows:

(i) *Preparation of sample solution.* Remove an accurately measured representative portion from each container immediately after thawing and reaching room temperature and dilute with water to obtain a solution containing 50 micrograms of cefuroxime per milliliter (estimated). Prepare the sample solution just prior to its introduction in the chromatograph.

(ii) *Calculation.* Calculate the milligrams of cefuroxime per milliliter of sample as follows:

$$\text{Milligrams of cefuroxime per milliliter} = \frac{A_u \times P_s \times d}{A_s \times 1{,}000}$$

where:

A_u=Area of the cefuroxime peak in the chromatogram of the sample (at a retention time equal to that observed for the standard);

A_s=Area of the cefuroxime peak in the chromatogram of the cefuroxime working standard;

P_s=Cefuroxime activity in the cefuroxime working standard solution in micrograms per milliliter; and

d=Dilution factor of the sample.

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(1) of that section.